

AF/1623

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

REINER et al

Atty. Ref.: 622-39

Serial No. 09/524,747

Group: 1623

Filed: March 15, 2000

Examiner: Howard V. Owens, Jr.

For: PHARMACEUTICAL COMPOSITIONS BASED ON DICLOFENAC

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November 3, 2003 NOV 06 2003

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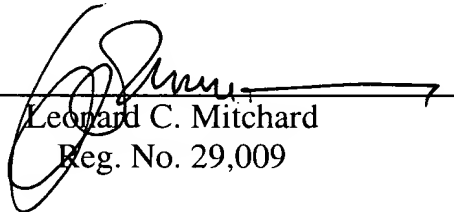
Attached is a completed Form PTO-1449 listing references in connection with this application. Also enclosed is a copy of each of those references.

The Examiner is requested to initial the attached PTO-1449, and to return a copy of the initialed document to the undersigned as an indication that the listed references have been considered and made of record.

Respectfully submitted,

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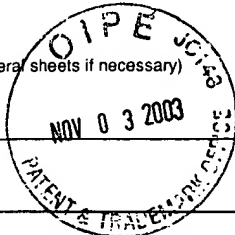
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U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
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FOREIGN PATENT DOCUMENTS

DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
6 0 466 650 A2	01/1992	EP			

OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)

1	Henry, D., et al; "Variability in risk of gastrointestinal complications with individual non-steroidal anti-inflammatory drugs: results of a collaborative meta-analysis"; BMJ; Vol. 312, pp. 1563-1566, (1996).
2	Walker, A.M.; "Quantitative studies of the risk of serious hepatic injury in persons using nonsteroidal antiinflammatory drugs"; Arthritis and Rheumatism, Vol. 40, No. 2, pp. 201-208 (1997).
3	Gutthann, S.P., et al; "Nonsteroidal anti-inflammatory drugs and the risk of hospitalization for acute renal failure"; Arch. Intern. Med., Vol. 156, pp. 2433-2439, (1996)
4	Amidon, G.L., et al; "A theoretical basis for a biopharmaceutic drug classification: The correlation of <i>in vitro</i> drug product dissolution and <i>in vivo</i> bioavailability"; Pharm. Research, Vol. 12, No. 3, pp. 413-420, (1995).
7	Neuvonen, P.J., "The effect of magnesium hydroxide on the oral absorption of ibuprofen, ketoprofen and diclofenac"; Br. J. Clin. Pharmacol. Vol. 31, pp. 263-266, (1991).
8	Neuvonen, P.J., et al; "Enhancement of drug absorption by antacids"; Clin. Pharmacokinet. 27 (2): pp. 120-128, (1994).
9	Neuvonen, P.J., et al; "Effect of magnesium hydroxide on the absorption of tolfenamic and mefenamic acids"; Eur. J. Clin. Pharmacol, 35: pp. 495-501, (1988).
10	Derendorf, H., et al; "Pharmacokinetics of diclofenac sodium after intramuscular administration in combination with triamcinolone acetate"; Eur. J. Clin. Pharmacol., 31:363-365 (1986).
11	Terhaag, B., et al; "Bioavailability of a new effervescent tablet of diclofenac"; Int. J. Clin. Pharmacol. Ther., 38:546:551 (2000).
12	Lotsch, J., et al; "Population pharmacokinetics of fast release oral diclofenac in healthy volunteers: relation to pharmacodynamics in an experimental pain model"; Pharmaceutical Research, Vol. 17, No. 1, pp. 77-84, (2000).
13	Marzo, A., et al; "Pharmacokinetics of Diclofenac after oral administration of its potassium salt in sachet and tableted formulations"; Arzneim. Forsch., 50:43-47 (2000).
14	Reiner, V., et al; "Increased absorption rate of diclofenac from fast acting formulations containing its potassium salt"; Arzneim. Forsch., 51:885-890 (2001).
15	Fourtillan, J.B., et al; "Etude pharmacocinetique du piroxicam chez l'homme sain"; Therapie, Vol. 38, pp. 163-170, (1983).
16	Brogden, R.N., et al; "Diclofenac sodium: A review of its pharmacological properties and therapeutic use in rheumatic diseases and pain of varying origin"; Drugs, 20: pp. 24-48, (1980).
17	Macia, M.A., et al; "Comparative bioavailability of a dispersible formulation of diclofenac and finding of double plasma peaks"; Int. J. Clin Pharmacol. Ther., 33:333-339 (1995).

*Examiner

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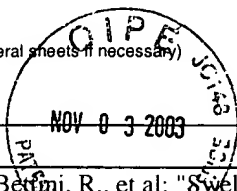
FILING DATE

GROUP

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1623

(Use several sheets if necessary)



- 18 Betti, R., et al; "Swelling force development as a result of hydrate formation in diclofenac sodium or nitrofurantoin tablets"; S.T.P. Pharma Sciences 10 (4) pp. 335-339, (2000).
- 19 Henrikson, P.A., et al; "Absorption and effect of diclofenac sodium after surgical removal of a lower wisdom tooth; Curr. Ther. Res., 31:30-26 (1982).
- 20 Degen, P.H., et al; "Pharmacokinetics of diclofenac and five metabolites after single doses in healthy volunteers and after repeated doses in patients"; Xenobiotica, 18:1449-1455 (1988).
- 21 Maggi, C.A., et al; "Comparative bioavailability of diclofenac hydroxyethylpyrrolidine vs diclofenac sodium in man"; Eur. J. Clin. Pharmacol., 38:207-208 (1990).
- 22 Mendes, G.B.B., et al; "Comparative bioavailability of two suspension formulations of potassium diclofenac in healthy male volunteers"; Int. J. Clin. Pharmacol. Ther., 32:131-135 (1994).
- 23 Crook, P.R., et al; "The pharmacokinetics of diclofenac sodium in patients with active rheumatoid disease"; Eur. J. Clin. Pharmacol., 21:331-334 (1982).
- 24 Willis, J.V., et al; "The pharmacokinetics of diclofenac sodium following intravenous and oral administration"; Eur. J. Clin. Pharmacol., 16:405-410 (1979).
- 25 Willis, J.V., et al; "The influence of food on the absorption of diclofenac after single and multiple oral doses"; Eur. J. Clin. Pharmacol., 19:33-37 (1981).
- 26 Riess, W., et al; "Pharmacokinetics and metabolism of the anti-inflammatory agent Volten" Scand. J. Rheumatol., Suppl. 22:17-29 (1978).
- 27 Physicians' Desk Reference; Novartis Pharmaceutical Corp., pp. 1830-1832 (2000).

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*Examiner

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